UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

MIMEDX GROUP, INC., Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; and ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, United States Food and Drug Administration, Defendants.	Case No.: 1:24-cv-01287-SEG

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

INTRODUCTION

Plaintiff MiMedx Group, Inc. manufactures a wound-care product called AXIOFILL. The Food and Drug Administration classified AXIOFILL as a "biological product." That classification subjects AXIOFILL to burdensome regulatory requirements, including premarket review. FDA should have classified AXIOFILL as a "361 HCT/P," a classification that will be explained below. A 361 HCT/P is subject to almost none of the regulatory burdens that apply to a biological product. MiMedx brings this action under the Administrative Procedure Act to set aside FDA's classification decision, which is contrary to law and arbitrary and capricious.

AXIOFILL is a dry powder consisting of extra-cellular matrix, or "ECM," from human placental tissue. ECM is a network of large molecules that provides structural support for cells throughout the body, akin to the frame of a house. To make AXIOFILL, MiMedx obtains placental disc tissue donated by mothers who have delivered healthy babies via C-section. It then processes the tissue to remove the cells and isolate the ECM (like stripping a house down to its frame). AXIOFILL is intended "to replace or supplement damaged or inadequate integumental tissue." AR.247.[1] In short, doctors apply AXIOFILL to wounds to provide a physical scaffold to support the growth of new cells.

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[1] Portions of the administrative record produced by FDA are cited by their Bates page number preceded by the prefix "AR."

Under FDA's regulations, AXIOFILL should be classified as a 361 HCT/P. A 361 HCT/P is a product consisting of human cells or tissues that is intended for implantation into a human recipient and meets certain criteria to be regulated solely under section 361 of the Public Health Service Act, meaning it is not subject to the distinct statutory and regulatory requirements that govern biological products. As relevant here, to qualify as a 361 HCT/P, a tissue-based product must be "minimally manipulated," meaning it must retain its "original relevant characteristics … relating to the tissue's utility for reconstruction, repair, or replacement." It also must be "intended" for "homologous use," meaning it "performs the same basic function or functions in the recipient as in the donor." 21 C.F.R. §§ 1271.10(a)(1)–(2), 1271.3(c), (f).

As MiMedx's submission to FDA demonstrated, AXIOFILL meets these requirements. It is composed of ECM that retains its original ability to serve as a scaffold for cellular growth, which satisfies the minimal-manipulation requirement. It also performs the same basic function—providing structural support for cells—in both the donor and the recipient, which satisfies the homologous-use requirement. In the decision under review, FDA did not dispute that the ECM in AXIOFILL retains its original relevant characteristics as ECM (minimal manipulation) or that it is intended to provide the same cellular scaffolding in the recipient that it provides in the donor (homologous use).

Instead, FDA chiefly concluded that AXIOFILL is more than minimally manipulated because it does not retain all the characteristics of a complete, intact placental disc, such as the ability to connect "fetal and maternal circulatory systems." AR.259. FDA's reasoning contravenes the regulations in multiple respects. The unit of analysis for assessing minimal manipulation is the HCT/P that is implanted into the patient—here, the ECM—not any larger tissue or organ from which that HCT/P was derived or extracted; and the characteristics of the tissue that must be preserved are those that contribute to reconstruction, repair, or replacement in the patient. That is why FDA considers isolated heart valves and corneas to be minimally manipulated even though they do not retain all the characteristics of an intact heart or eye. In the same way, FDA should have asked whether AXIOFILL retains the relevant characteristics of ECM, not those of an entire placental disc.

The Eleventh Circuit has chastised FDA for a similar error. In *United States v. US Stem Cell Clinic, LLC*, 998 F.3d 1302 (11th Cir. 2021), FDA concluded that stem cells extracted from adipose tissue (*i.e.*, body fat) did not qualify as 361 HCT/Ps because intact body fat provides a cushioning function, whereas isolated stem cells do not. The Eleventh Circuit disagreed and held that FDA should have "compare[d] stem cells to stem cells," not to the larger tissue from which they were extracted. *Id.* at 1311. So too here, FDA should have compared ECM to ECM, not to an intact placental disc. FDA brushed off

the *Stem Cell Clinic* decision because it focused on the homologous-use requirement, but the Eleventh Circuit's reasoning applies with equal force to the closely related and textually similar minimal-manipulation requirement.

In a brief footnote, FDA also suggested that AXIOFILL is not intended for homologous use, but it provided no meaningful explanation for that assertion. And to the extent FDA's conclusory footnote implied that AXIOFILL is not intended for homologous use because providing a scaffold for skin cells is a different "basic function" than providing a scaffold for placental cells, that explanation is contrary to decades of FDA precedent making clear that an HCT/P's "basic function" transcends any specific anatomic location.

FDA's treatment of products similar to AXIOFILL has also been wildly inconsistent. FDA did not reconcile its decision here with its decision two decades ago classifying an essentially identical wound-care product as a 361 HCT/P. Nor did FDA square its treatment of AXIOFILL with its longstanding position that demineralized bone matrix powder—which provides a scaffold for the growth of bone cells, similar to how AXIOFILL provides a scaffold for the growth of skin cells—is a 361 HCT/P. Complicating matters further still, while MiMedx's request for classification of AXIOFILL was pending, FDA classified a highly similar product as a device rather than a biological product. These zigzagging classification decisions are a textbook example of arbitrary and capricious decision-making.

BACKGROUND

A. FDA's Regulation of Cellular- and Tissue-Based Products

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and the Public Health Service Act, 42 U.S.C. § 201 *et seq.*, grant FDA authority to regulate certain categories of medical products, including drugs, devices, and biological products. FDA's classification of a product determines which part of FDA is primarily responsible for regulating the product, whether and to what extent the product is subject to premarket review, what registration requirements apply, and so on. In short, "[t]hroughout the lifecycle of a medical product, its treatment by the FDA depends upon its classification." *Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 634 (D.C. Cir. 2021).

In addition, section 361 of the Public Health Service Act (codified as 42 U.S.C. § 264(a)) authorizes FDA to issue regulations to prevent the spread of communicable diseases. Relying on that authority, FDA has established a "comprehensive … system of regulation" for human cells, tissues, and cellular- and tissue-based products, known as "HCT/Ps." 66 Fed. Reg. 5447, 5447–48 (Jan. 19, 2001). FDA has issued regulations, known as the "tissue rules," to govern HCT/Ps. *See* 21 C.F.R. §§ 1271.1–.440.

FDA defines HCT/Ps as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." *Id.* § 1271.3(d). HCT/Ps "have long been

transplanted in medicine for widespread uses—such as skin replacement after severe burns, tendons and ligaments to repair injuries, heart valves to replace defective ones, [and] corneas to restore eyesight." FDA, Proposed Approach to Regulation of Cellular and Tissue-Based Products at 6 (Feb. 28, 1997).

Because many HCT/Ps pose little risk to the public, FDA sought to enable manufacturers working in this area to "develop new therapies and products with as little regulatory burden as possible." *Id.* at 27. It therefore decided that "most HCT/Ps" would be "regulated solely under" section 361 of the Public Health Service Act and the tissue rules. 66 Fed. Reg. at 5449–51. Those rules require registration with FDA and govern matters such as the screening and testing of donors and the recovery, processing, storage, labeling, packaging, and distribution of HCT/Ps. *See* 21 C.F.R. §§ 1271.10(b), 1271.45–.320. They do not, however, require premarket review.

HCT/Ps that meet the criteria to be regulated solely under section 361 and the tissue rules are commonly called "361 HCT/Ps." 66 Fed. Reg. at 5449. HCT/Ps that do not meet these criteria are still subject to the tissue rules and are *also* regulated as drugs, devices, or biological products, all of which are subject to more onerous regulatory requirements. 21 C.F.R. § 1271.20. For example, it is generally unlawful to distribute a biological product without first obtaining a license from FDA. *See* 42 U.S.C. § 262(a).

To qualify as a 361 HCT/P, an HCT/P must meet four criteria, two of

which are relevant here. First, the HCT/P must be "minimally manipulated." 21 C.F.R. § 1271.10(a)(1). For "structural tissue" like ECM, FDA defines minimal manipulation as "processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement." *Id.* § 1271.3(f). Second, the HCT/P must be "intended for homologous use," *id.* § 1271.10(a)(2), which is defined as "repair, reconstruction, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor," *id.* § 1271.3(c).[2]

A product's sponsor (typically the manufacturer) can obtain a formal, binding determination from FDA as to the product's classification by submitting a Request for Designation, or "RFD." 21 U.S.C. § 360bbb-2(a); 21 C.F.R. § 3.7. Before doing so, the sponsor may obtain "informal, non-binding feedback" by submitting a Pre-Request for Designation, or "Pre-RFD." FDA, Guidance: How to Prepare a Pre-Request for Designation (Pre-RFD): Guidance for Industry at 3 (Feb. 2018). FDA's decision on a Request for Designation is final agency action reviewable under the APA. *Genus*, 994 F.3d at 636.

[2] FDA does not dispute that AXIOFILL satisfies the other criteria, so this motion does not discuss them in detail. Briefly, they state that the HCT/P may not be combined with prohibited articles and must either (i) not have a "systemic effect" and not depend on "metabolic activity of living cells" or (ii) comply with certain use limitations. 21 C.F.R. § 1271.10(a)(3)–(4).

B. MiMedx's Wound-Care Product, AXIOFILL

MiMedx is a pioneering biomedical company based in Marietta, Georgia. In September 2022, MiMedx launched AXIOFILL, a wound-care product consisting of "extracellular matrix" derived from human placental tissue.

All human tissue contains both living cells and extracellular matrix, or ECM—a network of large molecules that provides structural support for the surrounding cells. AR.241, 252.[3] AXIOFILL consists of ECM derived from donated human placental tissue. AR.245. The tissue is rinsed and soaked to wash away cellular components and other detritus, leaving the "decellularized" ECM intact. AR.245–47. After these steps, only ECM remains in the final product. AR.247. The ECM is then cut and ground into particles approximately 1 mm in diameter. AR.247. The resulting powder can be applied to wounds—including large, complex, or irregularly shaped wounds—to supply a physical ECM scaffold to support the growth of new cells. AR.247.

MiMedx determined that AXIOFILL met all the criteria to qualify as a 361 HCT/P. MiMedx therefore complied with all applicable requirements of the

[3] *See also, e.g.*, AR.217 ("The ECM is an acellular, protein-rich matrix that is essential for structural support and cellular attachment."); AR.223 ("The extracellular matrix (ECM) is a critical structural component of any tissue, including the integument."); AR.367 ("The extracellular matrix is an extensive three-dimensional molecular network that offers structural integrity and mechanical support to various tissues, including the skin …."); AR.369 ("The non-cellular portion of connective tissues is ECM, providing the physical scaffolding for the cells.").

tissue rules and did not seek approval or clearance from FDA before marketing AXIOFILL. *See Richfield v. PolarityTE, Inc.*, 2023 WL 3010208, at *2 (D. Utah Apr. 19, 2023) (FDA's regulations do not require "consultation with or approval by" FDA before marketing a 361 HCT/P).

C. MiMedx's Pre-Request for Designation

In early 2023, during an FDA inspection of MiMedx's facilities, the inspectors took the position that AXIOFILL was not a 361 HCT/P. Accordingly, in March 2023, MiMedx submitted a Pre-Request for Designation seeking an informal determination that AXIOFILL was properly classified as a 361 HCT/P. *See* AR.1–88.

FDA responded in October 2023 with its "preliminary assessment" that AXIOFILL did not meet the criteria to be classified as a 361 HCT/P. AR.100; *see* AR.99–106. Specifically, FDA stated that AXIOFILL "d[id] not appear" to be minimally manipulated because the processing of the donated placental tissue altered its "original relevant characteristics" relating to its "utility to act as a selective barrier that provides a transport function between different circulatory systems (e.g., the fetal and maternal circulatory systems)." AR.100–01. In a footnote, FDA stated that AXIOFILL "also does not appear to meet" the homologous-use requirement. AR.104 n.16. FDA concluded that AXIOFILL "appears to be a biological product" requiring "marketing authorization from the agency." AR.104, 106. FDA stated that this conclusion

was "preliminary" and invited MiMedx to "submit an RFD" to receive "a final determination with respect to [AXIOFILL's] classification." AR.106.

D. MiMedx's Request for Designation

In January 2024, MiMedx submitted a formal Request for Designation demonstrating that AXIOFILL satisfies all the criteria to be regulated as a 361 HCT/P. *See* AR.241–55. It explained that AXIOFILL is minimally manipulated because its processing preserves the ECM's capacity to serve as a scaffold for cellular growth and that AXIOFILL is intended for homologous use because the ECM performs the same basic function—providing structural support for surrounding cells—in the donor and the recipient. AR.248, 250.[4]

MiMedx responded in detail to FDA's preliminary assessment that AXIOFILL was more than minimally manipulated. It explained that FDA's assessment contravened the regulations in at least two respects. First, it focused on the wrong unit of analysis by asking whether AXIOFILL retains characteristics of the placental disc *as a whole*—such as its ability to connect maternal and fetal circulatory systems—rather than those of *the ECM*. AR.248–49. Second, FDA overlooked that even if the placental disc as a whole were the proper unit of analysis, its ability to connect maternal and fetal

[4] MiMedx also explained that AXIOFILL satisfies the other criteria because it is not combined with prohibited articles and does not have a systemic effect or depend on living cells for its primary function. AR.251.

circulatory systems would not be a "relevant characteristic" for purposes of the minimal-manipulation criterion because it has no bearing on AXIOFILL's utility for "reconstruction, repair, or replacement" in the recipient. AR.249–50.

MiMedx further explained that FDA's preliminary assessment was inconsistent with its treatment of similar products. In 2004, FDA classified an essentially identical wound-care product, consisting of ECM powder derived from human placental tissue, as a 361 HCT/P. AR.248, 252–54. And FDA has long taken the position that demineralized bone matrix ("DBM") powder is minimally manipulated, even though DBM powder functions similarly to ECM and does not retain all the characteristics of intact bone tissue. AR.255.

Finally, MiMedx noted that while FDA had provided "no explanation or analysis" supporting its suggestion that AXIOFILL "does not appear to meet" the homologous-use criterion, it seemed likely that FDA had been "led astray by the same errors" that infected its minimal-manipulation analysis. AR.250.

E. FDA's Final Decision

FDA issued its final decision on March 22, 2024, concluding that AXIOFILL is a biological product and not a 361 HCT/P. AR.256–69.

FDA doubled down on its assertion that for AXIOFILL to be considered minimally manipulated, it would have to retain the original characteristics of "the placental disc as a whole" that relate to "how [the placental disc] functions in the donor" rather than the original characteristics of the extracellular

matrix that relate to its utility for reconstruction, repair, or replacement in the recipient. AR.259–60. FDA thus claimed that AXIOFILL is not minimally manipulated because it is processed in a way that alters "the native placental disc's … utility to act as a selective barrier that provides a transport function between … the fetal and maternal circulatory systems." AR.259, 262. FDA did not dispute that the ECM in AXIOFILL retains the characteristics that allow it to serve as a scaffold for cellular growth—instead, it said this was irrelevant because "acting as a scaffold for the infiltration of cells" is not a "relevant characteristic of the placental disc" as a whole. AR.265.

FDA denied that its analysis was inconsistent with its treatment of similar products. It said the 2004 product it had approved as a 361 HCT/P consisted of ECM derived from a *portion* of the placental disc, whereas AXIOFILL consists of ECM derived from the *entire* placental disc; but it did not explain why that difference matters. AR.263–64. And it said its treatment of DBM powder "is based on factors that are specific to DBM products" but did not explain what those factors are. AR.266 (quotation marks omitted).

In addition to asserting that AXIOFILL is not minimally manipulated, FDA once again suggested in a footnote that AXIOFILL "does not appear to meet" the homologous-use criterion. AR.266 n.27.

Having refused to classify AXIOFILL as a 361 HCT/P, FDA concluded that AXIOFILL was properly classified as a biological product and not a device.

AR.267–69. FDA did not address its previous or contemporaneous classifications of similar products as devices rather than biological products.

LEGAL STANDARD

"Under the APA, [the Court] must 'hold unlawful and set aside agency action found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299, 1306 (11th Cir. 2021) (alterations adopted) (quoting 5 U.S.C. § 706(2)(A)). "[A] court may uphold agency action only on the grounds that the agency invoked when it took the action." *Michigan v. EPA*, 576 U.S. 743, 758 (2015). Accordingly, a court may "consider only the basis articulated by the agency itself" and must disregard any "*post hoc* rationalizations." *Bidi Vapor LLC v. FDA*, 47 F.4th 1191, 1202 (11th Cir. 2022) (quotation marks omitted).

"[T]he failure of an agency to comply with its own regulations constitutes arbitrary and capricious conduct." *Charter Fed. Sav. & Loan Ass'n v. Off. of Thrift Supervision*, 912 F.2d 1569, 1580 (11th Cir. 1990) (quotation marks omitted). When "there is only one reasonable construction of a regulation," a court "must give it effect, as the court would any law," and "has no business deferring to any other reading." *Kisor v. Wilkie*, 588 U.S. 558, 575 (2019). "[T]he possibility of deference can arise only if a regulation" is "genuinely ambiguous … after a court has resorted to all the standard tools of interpretation." *Id.* at 573. And even if a regulation is truly ambiguous, a court may not defer to the

agency's interpretation unless "an independent inquiry" into its "character and context" shows that it reflects the agency's authoritative or official position, its substantive expertise, and its fair and considered judgment. *Id.* at 576–79.[5]

Moreover, it is a "fundamental principle of administrative law that agencies must treat like cases alike." *Grayscale Invs., LLC v. SEC*, 82 F.4th 1239, 1242 (D.C. Cir. 2023). "Where an agency applies different standards to similarly situated entities and fails to support this disparate treatment with a reasoned explanation and substantial evidence in the record, its action is arbitrary and capricious and cannot be upheld." *Burlington N. & Sante Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 777 (D.C. Cir. 2005).

ARGUMENT

I. FDA's conclusion that AXIOFILL is more than minimally manipulated is contrary to law and arbitrary and capricious.

MiMedx showed in its submissions to FDA that AXIOFILL satisfies the minimal-manipulation criterion, 21 C.F.R. § 1271.10(a)(1). The reasons are straightforward. AXIOFILL consists of decellularized ECM. AR.241. For

[5] The Supreme Court recently clarified that "the APA means what it says" when it "specifies that courts, not agencies, will decide '*all* relevant questions of law' arising on review of agency action." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2261–62 (2024) (quoting 5 U.S.C. § 706). While *Loper Bright* held that courts may not defer to an agency's interpretation of a *statute*, its reasoning shows that the APA also prohibits courts from deferring to an agency's interpretation of a *regulation*, since "the interpretation of … regulations" is also a "question[] of law," *R.L. v. Miami-Dade Cnty. Sch. Bd.*, 757 F.3d 1173, 1181 (11th Cir. 2014).

structural tissue like ECM, minimal manipulation means "processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement." 21 C.F.R. § 1271.3(f)(1). ECM's utility for reconstruction, repair, or replacement is its ability to provide a scaffold for cellular growth. AR.248. MiMedx demonstrated, and FDA did not dispute, that the ECM in AXIOFILL retains its original relevant characteristics relating to its ability to serve as a cellular scaffold. AR.242–45, 248, 261–62. Therefore, AXIOFILL is minimally manipulated.

FDA nonetheless concluded that AXIOFILL is more than minimally manipulated. AR.258–66. That conclusion must be set aside for at least three reasons. *First*, FDA violated its own regulations by focusing on the wrong unit of analysis—the placenta as a whole rather than the ECM. *Second*, FDA also contravened the regulations by insisting that AXIOFILL retain *all* the tissue's original characteristics rather than only those that are "relevant" to "reconstruction, repair, or replacement." *Third*, FDA arbitrarily departed from its treatment of similar products as minimally manipulated. Each of these errors is independently sufficient to invalidate FDA's decision under the APA.

A. FDA contravened the regulations by misidentifying "the HCT/P" that must be minimally manipulated.

FDA's determination that AXIOFILL is not minimally manipulated was based on a fundamental legal error: It focused on the wrong unit of analysis.

FDA applied the minimal-manipulation requirement with reference to the placental disc from which AXIOFILL is derived rather than the ECM that comprises AXIOFILL. As FDA stated: "[Y]ou assert that 'the correct unit of regulatory analysis is the HCT/P itself—here, the placental disc ECM intended for implantation—not any larger tissue or organ from which the HCT/P was derived, processed, or extracted.' We disagree." AR.259 (quoting AR.249). This position is contrary to the regulations' plain meaning.

Identifying the correct unit of analysis is the logical and necessary first step in determining whether the 361 HCT/P criteria are satisfied. Under the regulation, for "[a]n HCT/P" to be "regulated solely under section 361," "[t]he HCT/P" must be "minimally manipulated." 21 C.F.R. § 1271.10(a)(1). The question thus arises whether "the HCT/P" that must be minimally manipulated is the ECM that comprises AXIOFILL itself (the product intended for implantation) or the placental disc from which that ECM is derived.

As an initial matter, the Eleventh Circuit has held that both a final product and the larger tissue or organ from which the product is derived may be considered "HCT/Ps." The regulations define HCT/Ps as "articles *containing or consisting of* human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." *Id.* § 1271.3(d) (emphasis added). So both AXIOFILL (which "consists of" the tissue "intended for implantation") and the intact placental disc from which AXIOFILL is

derived (which "contains" that tissue) can be considered HCT/Ps. *See Stem Cell Clinic*, 998 F.3d at 1308 (explaining that where a manufacturer processed adipose tissue to isolate the stem-cell-containing "stromal-vascular fraction" for implantation, "both adipose tissue and stromal-vascular fraction are HCT/Ps" because "[t]he adipose tissue *contains* the stromal-vascular fraction, which *consists of* cells intended for implantation into a patient"). Because both AXIOFILL and the intact placental disc can be considered HCT/Ps, the critical question is whether "the HCT/P" in the minimal-manipulation criterion refers to AXIOFILL or the intact placental disc.

The regulation provides a clear answer: The proper unit of analysis is the specific HCT/P that FDA is classifying for regulation. The regulation states that "[a]n HCT/P *is regulated* solely under section 361 … if *it* meets" the four enumerated criteria. 21 C.F.R. § 1271.10(a) (emphasis added). Each of those criteria then refers back to "*[t]he* HCT/P." *Id.* § 1271.10(a)(1)–(4) (emphasis added). So the article that must satisfy the four criteria is "the" HCT/P that "is" (or is not) eligible to be "regulated solely under section 361"—that is, the specific HCT/P that is intended for implantation in the patient, not the larger tissue or organ from which it was derived.

"[T]he broader context of" the tissue rules "as a whole" lends further support to this interpretation. *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997). Another provision of the rules states: "If you are an establishment that

manufactures an HCT/P that does not meet the criteria set out in § 1271.10(a), and you do not qualify for [an exception], your HCT/P will be regulated as a drug, device, and/or biological product." 21 C.F.R. § 1271.20. The only sensible reading of this provision is that the HCT/P that must "meet the criteria" is the same HCT/P that "will be regulated" (or not) as a drug, device, or biological product. Indeed, FDA cited this provision in classifying AXIOFILL (not an intact placental disc) "as a biological product." AR.266–67. In short, the 361 HCT/P criteria apply to the specific product intended for implantation, not some other, larger HCT/P from which that product is derived.

The Eleventh Circuit's analysis of the tissue rules in *Stem Cell Clinic* also confirms that the unit of analysis for the 361 HCT/P criteria must be the HCT/P that is intended for implantation. There, the defendant extracted adipose tissue from a patient, isolated the stromal-vascular fraction containing stem cells, and injected the stromal-vascular fraction back into the patient. 998 F.3d at 1305–06. The court first considered whether this treatment was exempt from the tissue rules under the "same surgical procedure" exception, which states that "an establishment that removes HCT/P's from an individual and implants such HCT/P's into the same individual during the same surgical procedure" is exempt from the tissue rules. 21 C.F.R. § 1271.15(b). The court agreed with FDA that the exception did not apply because the "natural" reading of the word "such," which "refer[s] back to an antecedent," is that "the

HCT/Ps implanted must be the same as the antecedent HCT/Ps—that is, the HCT/Ps that were removed." 998 F.3d at 1309. Because the defendant removed an HCT/P (adipose tissue), processed it, and then implanted a different HCT/P (the stromal-vascular fraction), the exception did not apply.

The Eleventh Circuit next considered the defendant's argument that its product satisfied the 361 HCT/P criteria. Although the court ultimately found that the product did not meet the homologous-use requirement due to the defendant's extravagant therapeutic claims, it agreed with the defendant that the proper unit of analysis was the stromal-vascular fraction that was intended for implantation, *not* the larger adipose tissue from which it was derived. *Id.* at 1310–11. As the court explained: "Unlike the same surgical procedure exception, the 361 HCT/P exception … do[es] not require that an establishment remove an HCT/P from a patient and reimplant 'such HCT/P' into the same patient. There is no reason, therefore, the court should not compare stem cells to stem cells." *Id.* at 1311. By the same logic, here, the FDA should have compared the processed ECM to the original ECM, not to the larger placental disc tissue from which it was derived.

FDA dismissed *Stem Cell Clinic* in a footnote because that case discussed homologous use rather than minimal manipulation. AR.261 n.15. But the Eleventh Circuit's reasoning applies equally to *all* of the 361 HCT/P criteria, which are all part of a single sentence in § 1271.10(a). Like the homologous-

use criterion, the minimal-manipulation criterion does not require removing and reimplanting the same HCT/P. So "[t]here is no reason … the court should not compare [ECM] to [ECM]." *Stem Cell Clinic*, 998 F.3d at 1311. FDA did not explain why it would make sense to interpret the phrase "[t]he HCT/P" in § 1271.10(a)(2), the homologous-use criterion, to mean the specific product intended for implantation while interpreting the very same phrase in § 1271.10(a)(1), the minimal-manipulation criterion, to mean the larger tissue from which the product was derived.[6]

For all these reasons, FDA's decision to apply the minimal-manipulation criterion to the placental disc as a whole rather than the ECM that comprises AXIOFILL is contrary to law and arbitrary and capricious. FDA's position that "the correct unit of regulatory analysis" is not "the HCT/P itself" but rather the "larger tissue or organ from which the HCT/P was derived," AR.259 (quotation marks omitted), contravenes both the regulatory text and the Eleventh Circuit's interpretation of that text in *Stem Cell Clinic*.

That mistake led FDA to the absurd conclusion that the ECM in AXIOFILL is more than minimally manipulated because, even though it

[6] Internally, FDA's Office of Therapeutic Products said it "d[id] not agree" with the holding of *Stem Cell Clinic* and that the Eleventh Circuit's decision "should not be the basis of any conclusions for this RFD" because it was still "being litigated through appeal." AR.751. That was incorrect: The decision had been issued three years earlier, and no party had sought further review.

retains the relevant characteristics *of ECM*, it does not retain the ability of *an intact placental disc* to provide a transportive barrier between "fetal and maternal circulatory systems." AR.259. FDA made the same basic error in *Stem Cell Clinic* when it concluded that stem cells extracted from body fat were non-homologous because they did not provide the cushioning that body fat as a whole provides. This is like saying a transplanted heart valve is more than minimally manipulated because it does not retain the ability of an intact heart to pump blood, or a transplanted cornea is more than minimally manipulated because it does not retain the ability of an intact eye to generate visual images. Yet heart valves and corneas are classic examples of 361 HCT/Ps. AR.687, 689.

FDA's counterargument is not persuasive. FDA cited the definition of minimal manipulation for structural tissue—"processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement," 21 C.F.R. § 1271.3(f)(1)—and argued that the word "original" means that this criterion cannot apply to "the finished product." AR.260. That is a *non sequitur*. Both placental disc ECM and an intact placental disc have "original" characteristics that may or may not have been altered by processing. One must determine what "the tissue" is that must be minimally manipulated before one can determine whether the "original relevant characteristics" of that tissue have been altered—but FDA's argument skips over the unit-of-analysis question entirely. As explained above,

the relevant tissue here is the ECM, not the placental disc as a whole.

B. FDA also contravened the regulations by misidentifying the "relevant characteristics" of the HCT/P.

Even if FDA were right that the entire placental disc is the proper unit of analysis, its decision would still be contrary to law because FDA misidentified the "relevant characteristics" of the placental disc. Here, the tissue's ability to link "fetal and maternal circulatory systems," AR.259, is not a *relevant* characteristic.

An HCT/P is minimally manipulated if processing "does not alter the original *relevant* characteristics of the tissue *relating to the tissue's utility for reconstruction, repair, or replacement*." 21 C.F.R. § 1271.3(f)(1) (emphasis added). So only characteristics that make the tissue useful for "reconstruction, repair, or replacement" must be preserved; other characteristics need not be preserved. And it is the *recipient*, not the donor, who needs "reconstruction, repair, or replacement."[7] Therefore, the minimal-manipulation requirement is met if the processing does not alter the original characteristics of the HCT/P

[7] FDA recognizes that each of these terms denotes a function performed in a tissue recipient, not a tissue donor. FDA defines "reconstruction" as "surgical reassembling or re-forming," such as "the reestablishment of the physical integrity of a damaged aorta." It defines "repair" as "the physical or mechanical restoration of tissues," such as the transplantation of skin "to a recipient in order to cover a burn wound." And it defines "replacement" as "substitution of a missing tissue or cell, for example, the replacement of a damaged or diseased cornea with a healthy cornea." AR.688.

that make it useful in the recipient. A characteristic that does not have utility for reconstruction, repair, or replacement in the recipient need not be preserved in order for an HCT/P to be considered minimally manipulated.

Yet in its decision on AXIOFILL, FDA misinterpreted the regulation to require preservation of characteristics of the placental disc that relate to its utility *in the donor*, even if they have no utility for reconstruction, repair, or replacement *in the recipient*. FDA said that "[o]riginal relevant characteristics of structural tissues generally include the properties of that tissue in the donor that contribute to … how that tissue functions in the donor." AR.259. On that basis, it said the "relevant" characteristics of the placental disc that had to be preserved were those "relating to its utility to act as a selective barrier" between "the fetal and maternal circulatory systems." AR.259.

When FDA asserted that the characteristics of structural tissue that must be preserved are those "that allowed it to achieve its structural role at the point of the tissue's origin, which is in the donor," AR.260, it once again misunderstood the function of the word "original." The word "original" means that the minimal-manipulation criterion compares certain characteristics as they exist *after* processing to how they existed *before* processing. But the word "original" does not answer the question of *which* characteristics are "relevant." It is the phrase "relating to the tissue's utility for reconstruction, repair, or replacement," 21 C.F.R. § 1271.3(f)(1), that defines which characteristics are

relevant. FDA did not explain why relevance should be interpreted to refer to utility *in the donor*. And it is hard to see how FDA could justify such an interpretation when the purpose of the HCT/P is to perform reconstruction, repair, or replacement *in the recipient* (that is, in the patient).[8]

Moreover, in addition to wrongly focusing on utility in the donor, FDA failed to explain how the placental disc's ability to connect maternal and fetal circulatory systems "relat[es] to" its "utility for reconstruction, repair, or replacement," 21 C.F.R. § 1271.3(f)(1), in *either* the recipient *or* the donor. Instead, FDA merely repeated that this characteristic of the placental disc is part of its structural role in the donor, AR.262, without tying that observation to the text of the regulation—which, again, is concerned *only* with characteristics that relate to "reconstruction, repair, or replacement."

FDA did not dispute that the ECM in AXIOFILL retains the characteristics that are relevant to its utility for reconstruction, repair, or replacement in the recipient. *See generally* AR.258–66. Instead, FDA insisted

[8] In internal documents, FDA acknowledged that it has routinely decided which characteristics of an HCT/P are "relevant" for purposes of minimal manipulation by considering the HCT/P's intended use in patients. *See, e.g.*, AR.277 (whether HCT/P was minimally manipulated depended on whether "processing … alter[ed] the characteristics relevant for its intended use"); AR.758–59 (similar). FDA did not acknowledge these precedents, much less try to distinguish them, when it asserted in the decision below that "relevant characteristics" are "the properties of th[e] tissue in the donor that contribute to … how that tissue functions in the donor." AR.259.

on making the native function of the intact placental disc the touchstone of the "relevant characteristics" that must be preserved for implantation. That fundamental misreading of the regulation renders FDA's decision unlawful.

C. FDA arbitrarily departed from its treatment of similar products as minimally manipulated.

FDA's decision is also arbitrary and capricious because it is inconsistent with FDA's treatment of similar products as minimally manipulated and FDA provided no meaningful explanation for the disparity. FDA thus violated the "fundamental principle of administrative law that agencies must treat like cases alike." *Grayscale*, 82 F.4th at 1242; *see NLRB v. Sunnyland Packing Co.*, 557 F.2d 1157, 1160 (5th Cir. 1977) ("[A]n agency must either conform itself to its own prior decisions or else explain the reason for its departure.").

1. *The 2004 Product.* In 2004, FDA classified an essentially identical product as a 361 HCT/P. In response to a Request for Designation, FDA issued a formal decision concluding that a product consisting of "decellularized particulate human placental connective-tissue matrix intended to replace or supplement damaged or inadequate integumental tissue" met all the criteria for regulation as a 361 HCT/P. AR.34–36, 342–44.[9] ("'Integumental tissue' refers to the body's outermost layer and protective covering, particularly the

[9] FDA produced two versions of the 2004 decision with differing redactions. The quoted language appears partly in one version of the document and partly in the other version.

skin." AR.247.) As MiMedx's RFD explained, AXIOFILL is "essentially the same as" the 2004 product, as both are composed of decellularized particulate ECM derived from human placental discs. AR.251–52. Therefore, FDA's conclusion that the 2004 product is minimally manipulated should have led the agency to conclude that AXIOFILL is also minimally manipulated.[10]

FDA provided no reasoned explanation for departing from its 2004 precedent. It offered only a single ground for distinguishing AXIOFILL from the 2004 product: The tissue source for the 2004 product is a portion of the placental disc called the "chorionic plate" (the fetal side of the placenta, as opposed to the maternal side or "basal plate," AR.368), whereas the tissue source for AXIOFILL is the entire placental disc, including the chorionic plate. AR.263–64. But FDA did not explain why this difference is relevant to the minimal-manipulation analysis.

It is, in fact, not relevant. As MiMedx explained and FDA did not dispute, the placental disc is "an interconnected matrix with inseparable zones," and "[r]egardless of zone," "the function of the ECM will be the same"—to provide "physical scaffolding for the cellular constituents." AR.252. And regardless of

[10] MiMedx also explained that a product called "Interfyl" appears, based on public statements by its manufacturer, to be the product that was the subject of the 2004 RFD. AR.252–53 & n.10; *see also* AR.18, 21, 39. And MiMedx presented scientific evidence, not disputed by FDA, that the "ECM in both products is capable of … acting as a scaffold for cellular ingrowth." AR.254.

any differences that might exist between the zones, FDA did not explain how the 2004 product could have been classified as minimally manipulated under the approach that FDA used with AXIOFILL, in which it insisted that the finished product must retain all the properties of the larger tissue from which it is derived. For example, FDA did not conclude (nor could it have) that the ECM in the 2004 product retained all the properties of the chorionic plate *as a whole*. In finding that product minimally manipulated, FDA clearly focused on *the ECM*, not the entire chorionic plate, as the relevant unit of analysis; yet FDA inexplicably refused to apply the same mode of analysis to AXIOFILL.

Internally, FDA's Center for Biologics Evaluation and Research acknowledged that the approach FDA took when evaluating AXIOFILL "does not appear to be consistent with" FDA's 2004 decision. AR.763. Yet in the RFD decision, FDA did not acknowledge or explain that inconsistency. Because FDA did not rationally explain its failure to treat like cases alike, its decision is arbitrary and capricious and must be set aside. *See Grayscale*, 82 F.4th at 1245–46; *Sharron Motor Lines, Inc. v. United States*, 633 F.2d 1115, 1117 (5th Cir. 1981) (agency's factual distinctions must be relevant to its rationale).

2. *Demineralized Bone Matrix Powder.* FDA also failed to provide a reasoned explanation for treating AXIOFILL as not minimally manipulated in light of its longstanding position that demineralized bone matrix powder *is* minimally manipulated. *See, e.g.*, 63 Fed. Reg. 26,744, 26,749 (May 14, 1998)

(concluding that "demineralized bone products … fall[] within the minimal manipulation definition"); FDA, Jurisdictional Update: Human Demineralized Bone Matrix (Feb. 16, 2018) (Doc. 1-15 at 2) ("Demineralized bone matrix alone … meets the criteria … for regulation solely under section 361."); AR.681.

Although they are derived from different types of tissue, there are clear parallels between AXIOFILL and demineralized bone matrix powder. DBM powder is made by processing bones to remove minerals and living cells, then grinding them into a fine powder that contains a molecular matrix capable of providing structural support for bone cells. Just as AXIOFILL's powdered ECM can serve as a scaffold for cellular growth in skin tissue, DBM powder can serve as a scaffold for cellular growth in bone. AR.255. At the same time, DBM powder does not retain all the characteristics of intact bones. If FDA had evaluated DBM powder using the same approach it applied to AXIOFILL, its position that DBM powder is minimally manipulated would make no sense.

FDA's attempt to distinguish its analysis of DBM powder from its analysis of AXIOFILL falls far short of what the APA requires. FDA first declared that its position on DBM powder is "based on factors that are specific to DBM products" and not applicable to other kinds of products. AR.266 (quoting AR.681). But FDA failed to state what those factors are or explain why they are relevant. A court "cannot even engage in meaningful review … unless [it is] told [w]hich factual distinctions separate arguably similarly

situated [products], and [w]hy those distinctions are important." *Pub. Media Ctr. v. FCC*, 587 F.2d 1322, 1331 (D.C. Cir. 1978). FDA then stated that "the original relevant characteristics of bone, in contrast to the placental disc … , relate to its utility to support the body and protect internal structures, including strength, and resistance to compression." AR.266. But FDA did not find that those characteristics of intact bone are preserved when it is processed into a powder, and they obviously are not.

In short, FDA's conclusion that DBM powder is minimally manipulated reflects a proper focus on the specific HCT/P intended for implantation rather than the larger tissue or organ from which that HCT/P is extracted. But FDA took the opposite approach when evaluating AXIOFILL. FDA is not free to apply the minimal-manipulation criterion differently for different products without providing a rational explanation. "[L]aw does not permit an agency to grant one person the right to do that which it denies to another similarly situated. There may not be a rule for Monday, another for Tuesday …." *Sharron Motor Lines*, 633 F.2d at 1117 (quotation marks omitted).

II. FDA's suggestion that AXIOFILL is not intended for homologous use is contrary to law and arbitrary and capricious.

While focusing its decision on the minimal-manipulation criterion, FDA said in a footnote that AXIOFILL also "appear[ed]" not to satisfy the homologous-use criterion. AR.266 n.27. Even if FDA's decision could be

sustained based on that tentative assertion, FDA's suggestion that AXIOFILL is not intended for homologous use contravenes the regulation.[11]

FDA defines homologous use as "the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor." 21 C.F.R. § 1271.3(c). As MiMedx explained and FDA did not dispute, a basic "function of ECM in the placental disc … is to provide a scaffold for cellular ingrowth"—the same function that AXIOFILL is intended to perform in patients. AR.250. AXIOFILL is therefore intended for homologous use. To the extent FDA concluded otherwise by asking whether AXIOFILL performs the same functions as an intact placenta, that would be contrary to the regulations and the *Stem Cell Clinic* decision for the reasons explained above.

FDA provided no other explanation for its decision that can bear scrutiny. In its footnote on homologous use, FDA stated that MiMedx had not provided evidence "that acting as a scaffold *for skin repair* is a basic function of the ECM component of the placental disc as it exists in the donor." AR.266 n.27 (emphasis added). If FDA meant to suggest that AXIOFILL does not perform the same basic function in the recipient as in the donor because

[11] FDA did not mention the other two 361 HCT/P criteria and did not dispute MiMedx's explanation that those criteria were satisfied. Internally, FDA acknowledged that those criteria were likely satisfied. AR.324, 730–31.

placental disc ECM exists inside the body and therefore does not provide a scaffold for *skin cells* specifically, that would be inconsistent with FDA's classification of the 2004 product—which also consisted of placental ECM used to provide a scaffold for skin repair, *see* AR.34–36, 763—as a 361 HCT/P. FDA provided no explanation for treating AXIOFILL differently.

That suggestion would also be inconsistent with decades of guidance regarding homologous use. FDA has long recognized that "[a]n HCT/P may perform the same basic function or functions even when it is not used in the same anatomic location where it existed in the donor." AR.691; *see* 66 Fed. Reg. at 5458 (stating that FDA "interpret[s] 'nonhomologous' narrowly" and "use of a structural tissue may be homologous even when it does not occur in the same location as it occurred in the donor"). For example, FDA has acknowledged that homologous uses include: (i) using tissue from the pericardium (the fluid-filled sac around the heart) to repair defects in dura mater (the membrane around the brain and spinal cord), where it performs the same basic function of "serv[ing] as a covering"; (ii) using tissue from the amniotic membrane (which surrounds a developing fetus) to protect the surface of the eye, where it performs the same basic function of "covering and offering protection"; and (iii) using decellularized skin tissue to reinforce a tendon, where it performs the same basic function of "provid[ing] support and protect[ing] the soft tissue structure from mechanical stress." AR.687, 690, 692.

As these examples demonstrate and the 2004 decision confirms, FDA has never interpreted homologous use so narrowly that providing a scaffold for cellular growth in one part of the body would not be considered the same basic function as providing a scaffold for cellular growth in a different part of the body. Regardless of location, the "basic function" of the ECM is the same: to provide structural support for surrounding cells. AR.250.

III. FDA's decision is also arbitrary because it has classified similar products as devices rather than biological products.

In addition to its erroneous determination that AXIOFILL is not a 361 HCT/P, FDA acted arbitrarily and capriciously when it classified AXIOFILL as a biological product rather than a device. "It is a familiar tenet of administrative law that review of the reasonableness of an [agency decision] includes consideration of the [agency's] consistency in deciding similar cases … whether handed down by the agency prior to or subsequent to the decision under review." *Delmarva Power & Light Co. v. FERC*, 770 F.2d 1131, 1143 n.9 (D.C. Cir. 1985) (quotation marks omitted); *see also, e.g.*, *Ala. Power Co. v. FCC*, 773 F.2d 362, 370–71 (D.C. Cir. 1985); *Carolina Power & Light Co. v. FERC*, 716 F.2d 52, 56 (D.C. Cir. 1983). While the Court need not reach this issue if it concludes that AXIOFILL is a 361 HCT/P, FDA's classification of AXIOFILL as a biological product is inconsistent with its classification of numerous similar products as devices—including a strikingly similar product that FDA

cleared as a device while the AXIOFILL RFD was pending before the agency.

A "device" is an article intended for medical use that "does not achieve its primary intended purposes through chemical action within or on the body" and "is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h)(1). In its RFD decision, FDA claimed that AXIOFILL does not satisfy that definition because it "retains components with chemical actions … that can supplement damaged or inadequate ECM, through the wound healing process, in the context of injured skin." AR.268. Specifically, FDA pointed to glycosaminoglycan ("GAG") chains, fibronectin, and laminin as ECM components that supposedly disqualify AXIOFILL from being classified as a device. AR.268.

FDA failed to acknowledge, however, that GAGs, fibronectin, and laminin are all basic components of ECM (*e.g.*, AR.367), and FDA has issued public decisions classifying many ECM products with similar components as devices. *See, e.g.*, FDA, 510(k) Clearance for InnovaMatrix PD, No. K211902 (Sept. 28, 2022), *available at* http://www.accessdata.fda.gov/cdrh_docs/pdf21/K211902.pdf ("decellularized extracellular matrix ... for the management of wounds" containing "laminin, fibronectin, … and sulfated [GAGs]"); FDA, 510(k) Clearance for Integra Meshed Bilayer Wound Matrix, No. K081635 (Feb. 26, 2020) (Doc. 1-16) ("wound care device" containing "collagen-[GAG] biodegradable matrix" that "provides a scaffold for cellular invasion").

During FDA's internal review of the AXIOFILL RFD, FDA's Center for Devices and Radiological Health acknowledged that FDA has classified as devices other "wound and burn dressings" that provide "scaffolding" for cellular growth. AR.326 n.27. As an example, the Center cited a device called Integra Dermal Regeneration Template, which "helps repair … damaged tissue" by "provid[ing] scaffolding (support framework) for … blood vessels and other cells to regrow," AR.326 n.27 (quotation marks omitted), and which, like AXIOFILL, contains GAGs.[12] The Center purported to distinguish the Integra device on the basis of "different processing, different final composition, and different intended use/claims." AR.326 n.27. But it did not explain these conclusory distinctions—and it even noted that, like the Integra device, AXIOFILL would claim only "physical scaffold properties," AR.326 (footnote omitted).

In its final decision, FDA did not adopt any of these proposed distinctions. Indeed, it did not even acknowledge, much less attempt to distinguish, the many ECM wound-care products that FDA has publicly classified as devices despite their obvious similarities to AXIOFILL. It thus failed to "either conform to its prior norms and decisions or explain the reason for its departure from such precedent," which is a basic "prerequisite[] to a

[12] *See* INTEGRA® Dermal Regeneration Template: Information for Patients and Their Families, *available at* https://www.accessdata.fda.gov/cdrh_docs/pdf/p900033s008d.pdf (cited at AR.326 n.27).

judicial finding that an agency's action is not arbitrary and capricious." *McHenry v. Bond*, 668 F.2d 1185, 1192–93 (11th Cir. 1982).

Underscoring the arbitrariness of FDA's approach, while the AXIOFILL RFD was pending, FDA issued a public decision granting another company clearance to market a substantially similar product, "Corplex P," as a device. *See* FDA, 510(k) Clearance for Corplex P (Feb. 2, 2024) (Doc. 1-20). FDA described Corplex P as a "particulate device" "derived from human umbilical cord extracellular matrix (ECM) and … indicated for the management of a range of acute and chronic wounds." *Id.* at 5.[13] Even though FDA was considering these two highly similar products at exactly the same time, it said nothing to explain why it classified AXIOFILL as a biological product and Corplex P as a device. This is textbook arbitrary and capricious decision-making, and it confirms that FDA's decision should not be allowed to stand.

CONCLUSION

The Court should grant MiMedx's motion for summary judgment, hold unlawful and set aside FDA's designation of AXIOFILL as a biological product, and declare that AXIOFILL meets the criteria to be regulated as a 361 HCT/P.

[13] Publicly available materials from Corplex P's manufacturer, which FDA presumably reviewed, make clear that Corplex P, like AXIOFILL, contains "ECM components such as collagen and [GAGs]." Doc. 1-18 at 3. Nor is that surprising, as FDA is aware that these are basic ECM components. *See* AR.367.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to LR 7.1(D), N.D. Ga., I hereby certify that the foregoing Plaintiff's Motion for Summary Judgment has been prepared in accordance with the font type requirements of LR 5.1, N.D. Ga., using 13-point Century Schoolbook font.

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